

### REMARKS

Claims 1-26 were pending. Claim 1 has been amended. To expedite prosecution, Applicants have cancelled claims 3-26. Applicants reserve the right to prosecute these or similar claims in the future. Applicants have also added new claims 27-41, and support for these new claims can be found throughout the specification and the claims as originally filed.

Applicants note with appreciation the Examiner's acknowledgment that SEQ ID NO: 60 and many of the other claimed SEQ ID NOS were free of the prior art and that all claimed SEQ ID NOS were searched within the scope of claims 1 and 2.

#### Rejection Under 35 U.S.C. § 112, Second Paragraph:

Claims 1 and 2 stand rejected as being indefinite. According to the Examiner, the term "substantially pure" is a relative term which renders the claim indefinite. The Examiner further states that the term "is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree." Applicants respectfully traverse.

MPEP 2173.01 states: "A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification."

Applicants draw the Examiner's attention to the following paragraph on page 6, line 25- page 7, line 11 of the specification as filed:

By "substantially pure polypeptide" or "substantially pure and isolated polypeptide" is meant a polypeptide (or a fragment thereof) that has been separated from components that naturally accompany it. Typically, the polypeptide is substantially pure when it is at least 60%, by weight, free from the proteins and naturally-occurring organic molecules with which it is naturally associated. Preferably, the polypeptide is a Bcl-X<sub>L</sub>-binding polypeptide that is at least 75%, more preferably, at least 90%, and most preferably, at least 99%, by weight, pure. A substantially pure Bcl-X<sub>L</sub>-binding polypeptide may be obtained, for example, by extraction from a natural source (e.g., a cell), by expression of a recombinant nucleic acid encoding a Bcl-X<sub>L</sub>-binding polypeptide, or by chemically synthesizing the polypeptide. Purity can be measured by any appropriate method, e.g., by column chromatography, polyacrylamide gel electrophoresis, or HPLC analysis.

Accordingly, the specification provides a standard for ascertaining the meaning of “substantially pure.” Further, methods of determining proportional weight of a polypeptide or protein relative to other proteins or organic molecules in a sample were well known in the art, for example, column chromatography or HPLC analysis as provided in the specification.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph:

Claim 1 stands rejected as failing to comply with the written description requirement. Applicants have amended claim 1 and respectfully submit that the amendment obviates the rejection.

Rejection Under 35 U.S.C. § 102(a)

Claim 1 stands rejected as being anticipated by Hammond et al. (Journal of Biological Chemistry, June 2001) or Giordano et al. (CA 2,343,602) or Ruben et al. (WO 01/22920).

Regarding Hammond et al., the Examiner states that this reference discloses SEQ ID NOS: 25, 33, 46, and 48. However, claim 1 as amended has the effective filing date of March 8, 2001, earlier than the publication date of Hammond et al. (June 2001). Accordingly, Hammond et al. cannot be used as 102(a) prior art against the present application. Further, three of the four named inventors of the present application are co-authors of Hammond et al. Applicants therefore reserve the right to submit a *In re Katz* declaration that the disclosure in Hammond et al. was not made “by another,” as is required for a 102(a) prior art reference.

Regarding Giordano et al. and Ruben et al., Applicants have amended claim 1 such that it is drawn in part to a substantially pure human BCL-X<sub>L</sub>-binding polypeptide consisting of the sequence of SEQ ID NO: 25. As noted by the Examiner, each of Giordano et al. and Ruben et al. discloses a protein comprising SEQ ID NO: 25, that is, neither reference teaches a polypeptide consisting of the sequence of SEQ ID NO: 25. Further, the Examiner has acknowledged that neither of these references teaches that the polypeptides comprising SEQ ID

NO: 25 bind to BCL-X<sub>L</sub>. Therefore, neither Giordano et al. nor Ruben et al. anticipates claim 1 as amended.

Further, Applicants note that Ruben et al. (WO01/22920) was published on April 5, 2001, after the effective filing date of the present application with respect to claim 1 as amended, which is March 8, 2001. Thus, Ruben et al. cannot be 102(a) prior art reference against the claim 1 as amended.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection Under 35 U.S.C. § 102(b)

Claim 1 stands rejected as being anticipated by Zhu et al. (WO 99/13075), because Zhu et al. discloses the protein p44 which comprises SEQ ID NO: 25. Zhu et al. teach the identification of genes in which their expression is either induced or repressed upon either cytomegalovirus infection or interferon treatment. Zhu et al. makes no mention of BCL-X<sub>L</sub>. As discussed above, claim 1 has been amended such that it is drawn in part to a substantially pure human BCL-X<sub>L</sub>-binding polypeptide consisting of the sequence of SEQ ID NO: 25. Accordingly, Zhu et al. does not anticipate claim 1 as amended.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection Under 35 U.S.C. § 102(e)

Claim 1 stands rejected as being anticipated by Brissette et al. (WO 03/38130) or Tang et al. (WO 03/31595). Specifically, the Examiner states that Brissette et al. discloses a protein comprising SEQ ID NO: 18 at residues 555-582 and the SREBP-1 protein comprising SEQ ID NO: 22 at residues 594-620 and that Tang et al. discloses a protein comprising SEQ ID NO: 45.

Applicants respectfully draw the Examiner's attention to the provisional application 60/274,526, which discloses, among many other SEQ ID NOS, SEQ ID NOS: 18, 22, and 45

and from which the present application claims priority. Thus, claim 1 as amended has the effective filing date of March 8, 2001.

However, Brissette et al. was published on May 8, 2003, and the earliest priority date for this application is October 31, 2001. Similarly, Tang et al. was published on April 17, 2003, and the earliest priority date for this application is October 12, 2001. Therefore, neither Brissette et al. nor Tang et al. can be used as 102(e) prior art against claim 1 as amended.

Accordingly, Applicants respectfully request withdrawal of this rejection.

In view of the above amendment and remarks, Applicants believe that the pending claims are in condition for allowance.

Applicants believe no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. COTH-P01-518 from which the undersigned is authorized to draw.

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Respectfully submitted,

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